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EXAMINER	
HUMPHREY, LOUISE WANG ZHIYING	

ART UNIT	PAPER NUMBER
1648	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/571,882	BARNETT ET AL.	
	Examiner	Art Unit	
	LOUISE HUMPHREY	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 May 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-18,26-28,30-41,43-57,60,61,63-73,79-82 and 84-90* is/are pending in the application.

4a) Of the above claim(s) *2,5,6,9,35-41,43-57,60,61,63-73,81 and 90* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3,4,7,8,10-18,26-28,30-34,79,80,82 and 84-90* is/are rejected.

7)☒ Claim(s) *10,12,16,27,84 and 88* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *15 March 2006* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *12/30/08*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

This Office Action is in response to Applicant's election filed on 06 May 2009. Claims 19-25, 29, 42, 58, 59, 62, 74-78 and 83 have been cancelled. Claims 1-18, 26-28, 30-41, 43-57, 60, 61, 63-73, 79-82 and 84-90 are pending.

Election/Restriction

Applicant's election with traverse of Group I, claims 1-18, 26-28, 30-34, 79-82 and 84-89, in the reply filed on 6 May 2009 is acknowledged. The traversal is on the ground that it would not constitute an undue burden to examine all the groups concomitantly. This is not found persuasive because applicants have not argued with particularity the basis for the requirement for restriction, but have merely asserted that the subject matter overlaps and that no burden of search is involved. Even though the searches may overlap, they are not coextensive and each requires its own search and considerations of other patentability issues. In other words, overlap of subject matter does not automatically translate into coextensive searches that are not a burden on the USPTO.

The requirement is still deemed proper and is therefore made FINAL.

Claims 1-18, 26-28, 30-41, 43-57, 60, 61, 63-73, 79-82 and 84-90 are pending.

Claims 2, 5, 6, 9, 35-41, 43-57, 60, 61, 63-73, 81 and 90 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention and species, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 06 May 2009.

Claims 1, 3, 4, 7, 8, 10-18, 26-28, 30-34, 79, 80, 82 and 84-90 are currently examined.

Information Disclosure Statement

Applicant's Information Disclosure Statements (IDS) filed 30 December 2008 has been received and entered into the application. As reflected by the attached, completed copy of form PTO-1449A, the Examiner has considered the cited reference.

Claim Objections

Claims 10, 12, 16, 27, 84, and 88 are objected to because of the following informalities:

Claim 10 is objected to because of the redundant phrase “analogous to the analogous” in line 7.

Claims 12, 16 and 84 are objected to because of grammatical errors: for example, the sentence parts, “the polynucleotide component” and “the polypeptide component,” are incongruent with the phrase “HIV envelope peptides.”

Claim 27 and 88 are objected to because of the improper format for reciting a protein name, which should be a three-letter name comprising a capitalized first letter followed by two lowercase letters, *i.e*. “Vif, Vpr, Vpu, Tat, Rev and Nef,” according to the nomenclature rules known in the art. Claim 27 is further objected to for failing to define the acronym "Prot," “Int” and “RT” at the first occurrence in the claims. Applicant may

consider amending the claims to recite --protease (PR), integrase (IN), reverse transcriptase (RT)-- at line 3 to 4 of the claim for clarity.

Appropriate correction is required.

Claim Rejections - 35 USC § 112, 2nd ¶

The following is a quotation of the second paragraph of 35 U.S.C. §112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 18 and 26 are rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 18 recites the limitation "alteration or mutation" in the second line. There is insufficient antecedent basis for this limitation in the claim.

Claim 26 is rejected for depending from claim 18.

Clarification and/or correction are required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. §102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 3, 4, 7, 8, 10-12, 16, 27, 28, 32-34, 80, 82, 84, 88 and 89 are rejected under 35 U.S.C. §102(b) as being anticipated by Barnett *et al.* (1997).

The instant claims are directed to a composition comprising a polynucleotide component and a polypeptide component comprising one or more HIV immunogenic polypeptides, wherein the polynucleotide encodes an analogous HIV immunogen of a different strain of a different subtype and further comprises a transcription promoter.

Barnett *et al*. teaches immunization composition comprising a plasmid comprising a CMV promoter and DNA sequence for HIV envelope protein, gp120, from strains CM235 (Thai subtype E) and US4 (North American subtype B), and further comprising a recombinant subunit protein of HIV-1 gp120 from strains CM235 and SF2 (page 869, right column, HIV gp120 plasmids and recombinant gp120 protein). The Thus, the instant invention is anticipated by Barnett *et al*.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. §103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 13, 17, 18, 26, 79 and 85-87 are rejected under 35 U.S.C. §103(a) as being unpatentable over Barnett *et al.* (1997) in view of Aldovini *et al.* (US 5,861,282, 19 January 1999) and Surman *et al*. (2001).

The instant invention is further limited to an HIV synthetic polynucleotide component comprising an alteration or mutation and an analogous HIV polypeptide, of a different subtype, expressed on a virus like particle (VLP).

The relevance of Barnett *et al.* is set forth above. Barnett *et al.* does not disclose alteration or mutation in the polynucleotide and VLP.

Aldovini *et al.* discloses alteration in a HIV nucleotide sequence and non-infectious immunogenic HIV particles (Abstract). Specifically, Aldovini *et al.* suggests mutations or deletions in the gp160 cleavage site to retain the gp120 antigen, which blocks the processing of the gp160 envelope precursor to gp120 and gp41 and reduces the "shedding" of gp120 antigen. See column 8, lines 1-21. Aldovini *et al.* further suggests removing Env glycosylation sites to improve antigenic or immunogenic properties. See column 8, lines 52-56. Furthermore, Aldovini *et al.* discloses combining HIV particles containing a spectrum of various Env proteins for wider protection or more specific detection of various strains of HIV. See column 8, lines 47-52.

Aldovini *et al*. does not explicitly disclose the benefit of deleting glycosylation sites in HIV Env, the exposure of CD4 or coreceptor binding sites. However, Surman *et al*. discloses that the epitopes of CD4 binding regions are heavily bordered by glycosylation sties. See Abstract and page 4590, right column, last paragraph.

Therefore, removal of the glycosylation sites renders strings of epitopes that are only the CD4 binding regions.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the composition of Banett *et al*. so as to include virus like particles for better presentation of the HIV envelope peptide and mutate the HIV Env sequence by deleting the glycosylation sites that exposes a CD4 binding region. One having ordinary skill in the art would have been motivated to make such a modification to improve the antigenic or immunogenic properties as per Aldovini's suggestion. There would have been a reasonable expectation of success, given that VLP is a vehicle for protein expression known in the art, as taught by Aldovini *et al*., and the heavy glycosylation in the epitope regions as disclosed by Surman *et al*. Thus, the invention as a whole was clearly *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Claims 13-15 are rejected under 35 U.S.C. §103(a) as being unpatentable over Barnett *et al.* (1997) in view of Corbet *et al.* (2000).

The instant invention is further limited to an HIV codon-optimized polynucleotide component and an analogous HIV polypeptide of a different subtype.

The relevance of Barnett *et al.* is set forth above. Barnett *et al.* does not disclose codon-optimization of the HIV polynucleotide.

Corbet *et al.* suggests codon-optimized HIV-1 envelope genes by removal of the internalization signals and the exchange of the highly biased AT-rich HIV codon usage

with that of highly expressed GC-rich human genes, which renders the envelope expression Rev-independent and improves the expression of the humanized HIV envelope protein in mammalian cell lines. See Abstract and pages 1997-1998, Introduction. Corbet *et al.* specifically discloses the benefit of increased specific cellular and humoral immune response. See page 2002, right column.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the composition of Banett *et al*. so as to optimize the codons in the polynucleotide sequence(s) as suggested by Corbet *et al*. One having ordinary skill in the art would have been motivated to make such a modification to improve the expression of the HIV antigens in order to enhance the immune responses as per Corbet's suggestion. Thus, the invention as a whole was clearly *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Claims 30 and 31 are rejected under 35 U.S.C. §103(a) as being unpatentable over Barnett *et al.* (1997) in view of Sailaja *et al.* (March 2003).

The instant invention further comprises an additional antigenic polynucleotide or polypeptide that is not derived from an HIV-1 strain.

The relevance of Barnett *et al.* is set forth above. Barnett *et al.* does not disclose an additional antigenic polynucleotide or polypeptide that is not derived from an HIV-1 strain.

Sailaja *et al.* suggests adding a polypeptide antigen, the extracellular domain of Fms-like tyrosine kinase receptor-3 ligand (FLex), or the DNA encoding FLex, to the

HIV-1 Env, in order to obtain long-term maintenance of gp120-specific immune responses through dendritic cell expansion. See page 2497, left column, the first two paragraphs.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine or fuse the HIV *env* polynucleotide or Env polypeptide of Barnett *et al.* with the FLex polypeptide or FLex coding sequence of Sailaja *et al.* so as to augment the HIV Env immune response as suggested by Sailaja *et al.* Thus, the invention as a whole was clearly prima facie obvious to one of ordinary skill in the art at the time the invention was made.

Conclusion

No claim is allowable.

Applicant is reminded that any amendment must point to a basis in the application as filed so as not to add new matter. See MPEP §714.02 and §2163.06.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Louise Humphrey, Ph.D. whose telephone number is 571-272-5543. The examiner can normally be reached on Mon-Fri, 9:30 am - 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms can be reached on 571-272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/L. H./
Examiner, Art Unit 1648

/Jeffrey S. Parkin/
Primary Examiner, Art Unit 1648

29 June 2009